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Food Safety And Inspection Service
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AUDIT REPORT FOR ARGENTINA

MARCH 30 THROUGH APRIL 18, 2000

December 20, 2000

INTRODUCTION

Background

This report reflects information that was obtained during a review of Argentina's meat inspection system from March 30 through April 18, 2000. Eight of the 32 establishments certified to export meat to the United States were audited.

The last audit of the Argentinean meat inspection system was conducted in June 1999. Twelve establishments were audited: eleven were acceptable, and one was evaluated as acceptable/re-review. The principal concerns with the system at that time were the following:

1. Ineffective maintenance program in Est. 1378

2. Water splash from wall at carcass wash in Est. 1373

3. Bruise trim on carcass inadequate in Ests. 1113, 1378, and 2676

These deficiencies were all corrected at the time of this audit.

Beef is exported to the U.S., fresh if it has a pH of 5.8 or less in no more than 60 hours, or if it is cooked. No uncooked pork or poultry is eligible.

During calendar year 1999, Argentina exported over 103 million pounds of beef and about 26 million pounds of beef so far in 2000 to the U.S. Port-of-entry rejections were for processing defects (0.2% of the total), contamination (0.4%), pathological defects (1.1%), and transportation damage and missing shipping marks (0.35% combined), unsound condition (.14%).

PROTOCOL

This on-site review was conducted in four parts. One part involved visits with Argentinean national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. The selection of establishments was based on previous problems, volume and problems of imported product, and some were selected randomly. The third part was conducted by on-site visits to establishments. The fourth was a visit to the laboratory performing analytical and microbiological testing of field samples for the national residue testing program and microbiological testing programs for the presence of microbiological contamination with *Salmonella*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Argentina's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Based on the performance of the individual establishments, Argentina's "In-Plant Inspection System Performance" was evaluated as In-Plant System Controls in Place.

Effective inspection system controls were found to be in place in all of the establishments audited and all eight were rated as acceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

Entrance Meeting

On January 20, an entrance meeting was held at the Buenos Aries offices of the Argentina Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA), and was attended by Dr. Eduardo Cohen Arazi, National Director of Agri-Food Fiscalization; Dr. Andres Schnoller, Director of Inspection of Animal Orgin Foods; Dr. Oscar Lernoud. Supervisor of

Exports to the United States; Mr. Gustavo Idigoras, Coordinator of International Relations and Dr. M. Douglas Parks, International Audit Staff Officer, USDA. Topics of discussion included the following:

1. Compliance and enforcement

2. Inspection service training

3. Various requests from USDA Policy, e.g. species testing, residue questionnaire. delistment and relistment methodology, microbiology testing to include *Listeria* testing and laboratory responsibilities.

4. On-site visits and in-plant records audit.

5. Establishment records audits in the central office.

6. Itinerary

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. review of Argentina's inspection system in June 1999.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for a records review. This records review was conducted in the offices of the meat/poultry inspection headquarters. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogens reduction and other food safety initiatives such as SSOPs, HACCP programs, generic E. coli testing and Salmonella testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.

- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result of the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Argentina as eligible to export meat products to the United States were full-time SENASA employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Thirty-two establishments were certified to export meat products to the United States at the time this audit was conducted. Eight establishments were visited for on-site audits. In all eight establishments visited, both SENASA inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Corrective actions were prompt and effective.

Laboratory Audit

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected.

1. Government oversight of accredited, approved, and private laboratories. (if any)
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The National Laboratory for Technical Services in Buenos Aries was audited on April 11, 2000. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recovery, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done. In the laboratory, a stock solution available for use was outdated. The solution was removed and a new solution was to be put in it's place and the dates of other solutions were to be checked. It was explained that the analyst probably would have caught this before it was used.

The check sample program did meet FSIS requirements. In the laboratory, analysts are given samples one time per month for qualitative determinations and once a year for quantitative determination. They also have an inter-laboratory check program with Switzerland.

Argentina's microbiological testing for *Salmonella* was being performed in this government laboratory. Both residue testing and *Salmonella* testing is being done in the same laboratory.

Establishment Operations by Establishment Number

The following operations were being conducted in the six establishments:

Beef slaughter and boning only - three establishments (1113,1378 and 2062)
Beef slaughter, boning and canning – two establishments (89 and 13)
Beef slaughter, boning and cooked frozen – two establishments (1373 and 1921)
Beef processing only, cooked frozen – one establishment (249)

SANITATION CONTROLS

Based on the on-site audits of establishments, Argentina's inspection system had controls in place for pre-operational and operational sanitation in all departments. The records of monitoring of these functions was in place and adequate.

Sanitation Standard Operating Procedures (SSOP)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were audited and found to meet the basic FSIS regulatory requirements with only occasional minor variations.

Cross Contamination

Except as otherwise noted, all the establishments visited met U.S. requirements for cross contamination.

1. Contamination Control. The following were minor variations: condensate above product trafficways in Ests. 13, 17, 18, and 1373; poor dressing procedure in the slaughter department in Ests. 13,18 and 1921; dirty viscera pans returned for use in Ests. 18, 1113 and 1921; failed preoperational sanitation, as evidenced by a dead fly in pooled dirty water on a table ready-for–use in the boning room of est. 1113 and a ground product mixer ready-for-use with residues from previous day's use in est. 1373; slaughter equipment not being sanitized between uses, leg clipper in est. 13 and carcass restrainer in est. 2062; extensive peeling and flaking paint in all carcass coolers and hallways in est. 89; temperature of boning room 14 degrees C and still operating where the program calls for no more than 10 degrees C.

These deficiencies were all corrected immediately by inspection and company personnel.

ANIMAL DISEASE CONTROLS

Argentina's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, humane handling and slaughter, condemned and restricted product control, and procedures for sanitary handling of returned and rework product. This included visual examination of all feet and lips of all slaughtered animals at the time of slaughter. This was done to guard against and detect any lesions of Foot and Mouth Disease.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. There is an identification and trace back system in place for any disease problems or positive residues revealed.

RESIDUE CONTROLS

Argentina's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Argentinean inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the Argentinean inspection system had controls in place to ensure that adequate controls were in place in the processing departments except for the following minor variations:

1. Carcasses presented to pre-boning trim had feces and multiple hairs in Ests. 1373 and 2062.
2. Boxes for vacuum packaged product were exposed and stored on an elevator with dust and debris in Est. 89.
3. Improper bung drop procedure in Ests. 13 and 1378.
4. Eviseration table coming up for re-use with residues from previous uses in Est. 1921.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements with only occasional minor variations. These minor variations were:

1. Some HACCP plans included points of sanitation that should be in the SSOP program (Est. 1378).
2. A time period was not linked to the carcass cooling temperature and a CCP was not monitored as frequently as the plan specified in Est. 1373.

3. No validation procedures in the plan in Est 249.
4. CCP's were too general and not specific enough in Est. 2062.

Testing for Generic *E. coli*

Argentina has adopted the FSIS regulatory requirements for *E. coli* testing. Seven of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements, with only occasional minor variations. The only minor deviation found was that several establishments were not recording preventative action.

Additionally, establishments had adequate controls in place to prevent meat products intended for Argentinean domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, the SENASA system controls [ante- and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other countries for further processing] were in place and effective in ensuring that products produced by the establishments were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Seven of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Argentina has adopted the FSIS regulatory requirements for *Salmonella* testing. The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements, with only occasional minor variations. Some of those minor variations were:

1. The carcass for sampling was not selected randomly in Est. 143.
2. The selected carcass was always cooled in a pre-selected spot and not left in the carcass population in Est. 1113.

Species Verification Testing

At the time of this audit, Argentina was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed by the Argentinean equivalent of Circuit Supervisors. All were veterinarians with experience. Dr. Andre Schnoller was in charge of the slaughter and processing establishments.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were not announced in advance, and were conducted, at times by individuals and at other times by a team of reviewers, at least once monthly, and sometimes two or three times within a month. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the central SENASA offices in Buenos Aries, and were routinely maintained on file for a number of years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, the supervisor conducts an in-depth review, and the results are reported to Drs Andres Schnoller and Oscar Lernoud; they formulate a plan for corrective actions and preventive measures.

After observing the internal reviewers' activities in the field, the auditor was confident in their professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Argentina's internal review program as a whole.

Enforcement Activities

Material about enforcement and compliance was gathered and forwarded to the International Policy Division in Washington, D.C. There was a discussion about people who were convicted of violations of the meat and poultry laws in Argentina being able to re-enter into some phase of the business. It was explained to me that once these people paid their debt to society, fines and/or confinement time, they were free to enter any business that they desire and there was no law against this.

Exit Meetings

An exit meeting was conducted in Buenos Aries on April 18, 2000. The Argentinean participants were Mr. Gustavo Idigoras, Coordinator de Relaciones Internacionales: Dr. Eduardo Cohen Arazi, Director Nacional de Fiscalizacion Agroalimentaria; Dr. Andres Schnoller, Director de Fiscalizacion de Products de Origen Animal; Dr. Oscar Lernoud, Veterinario, Direccion of U.S. Export Fiscalizcion; Dr. Eduardo Greco, Director de Epidemiologia; Mr. Victor Avigliano, Abogado, Direccion de Juridicos; and Dr. M. Douglas Parks, International Audit Staff Officer, USDA. The following topics were discussed:

1. The residue questionnaire status was discussed and it was stated that it had been returned to USDA in a timely manner.
2. Species testing was discussed and an exemption has been applied for through the Embassy to USDA.
3. Delistment procedures were discussed and they are consistent with our expectations.
4. Inspector and veterinarian training information was furnished to the auditor and relayed to headquarters.
5. Animal disease information was centered around Foot and Mouth Disease, the history and status of this disease in Argentina was the main subject.
6. Compliance and enforcement was discussed with a legal representative of their department and the results can be seen under the topic "Enforcement Activities".
7. Laboratory procedures and results of the laboratory audit were discussed emphasizing microbiological and residue testing
8. Ratings of establishments and deficiencies were discussed in detail as they related to the plants that were audited.
9. Deficiencies were discussed as well as the methodology now used in the audit and no major deficiencies were found in the overall program.

CONCLUSION

The inspection system of Argentina was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Eight establishments were audited and all eight were found to be acceptable. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. M. Douglas Parks
International Audit Staff Officer

(Signed) *Dr. M. Douglas Parks*

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing
D. Data collection instrument for *Salmonella* testing
E. Laboratory audit form
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report – No comments submitted by country.
H. FSIS response(s) to the Foreign Country Comments(when it becomes available)

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used included the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
2062	√	√	√	√	√	√	√	√
13	√	√	√	√	√	√	no	√
1373	√	√	√	√	√	√	no	√
89	√	√	√	√	√	√	√	√
249	√	√	√	√	√	√	no	√
1378	no	√	√	√	√	√	√	√
1921	√	√	√	√	√	√	√	√
1113	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. TIF-119) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or does not include records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. act's are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
2062	√	√	√	√	√	√	no	√	√	√	√	√
13	√	√	√	√	√	√	√	√	√	√	√	√
1373	√	√	√	√	√	√	no	√	√	no	√	√
89	√	√	√	√	√	√	√	√	√	√	√	√
249	√	√	√	√	√	√	√	√	no	no	√	√
1378	√	√	√	√	√	√	√	√	√	√	√	√
1921	√	√	√	√	√	√	√	√	√	√	√	√
1113	√	√	no	√	no	√	√	√	√	√	√	√

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an Equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6, Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
2062	√	√	√	√	√	√	√	√	√	√
13	√	√	√	√	√	√	no	√	√	√
1373	√	√	√	√	√	√	no	√	√	no
89	√	no	√	√	√	√	√	√	√	√
249	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
1378	√	√	√	√	√	√	√	√	√	√
1921	√	√	√	√	√	√	√	√	√	√
1113	√	√	√	√	√	√	no	√	√	√

Attachment D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
2062	√	√	√	√	√	√
13	√	√	√	no	√	√
1373	√	√	N/A	√	√	√
89	√	√	N/A	√	√	√
249	N/A	N/A	N/A	N/A	N/A	N/A
1378	√	√	N/A	√	√	√
1921	√	√	√	√	√	√
1113	√	√	N/A	√	√	√